RENOCAL-76 - diatrizoate meglumine and diatrizoate sodium injection, solution
Bracco Diagnostics Inc.,

NOT FOR INTRATHECAL USE

DESCRIPTION

RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) is a radiopaque contrast agent for intravascular use supplied as a sterile, aqueous solution. Each mL provides 660 mg diatrizoate meglumine and 100 mg diatrizoate sodium with 0.1 mg edetate calcium disodium as a sequestering agent. The pH has been adjusted to 6.0-7.7 with sodium carbonate and sodium hydroxide or hydrochloric acid. Each mL contains approximately 3.69 mg (0.16 mEq) sodium and 370 mg of organically bound iodine. The viscosity of the solution is 15 cps at 25°C and 9.1 cps at 37°C. It is hypertonic to blood with an osmolality of 1870 mOsm/kg. At the time of manufacture, the air in the container is replaced by nitrogen.

CLINICAL PHARMACOLOGY

Following intravascular injection, RenoCal-76 is rapidly transported through the bloodstream to the kidneys and is excreted unchanged in the urine by glomerular filtration. When urinary tract obstruction is severe enough to block glomerular filtration, the agent appears to be excreted by the tubular epithelium.
Renal accumulation is sufficiently rapid so that the period of maximal opacification of the renal passages may begin as early as five minutes after injection. In infants and small children excretion takes place somewhat more promptly than in adults, so that maximal opacification occurs more rapidly and is less sustained. The normal kidney eliminates the contrast medium almost immediately.
In nephropathic conditions, particularly when excretory capacity has been altered, the rate of excretion varies unpredictably, and opacification may be delayed for 30 minutes or more after injection; with severe impairment opacification may not occur. Generally, however, the medium is concentrated in sufficient amounts and promptly enough to permit a thorough evaluation of the anatomy and physiology of the urinary tract. After intramuscular injection, the contrast agent is promptly absorbed and normally reaches the renal passages within 20 to 60 minutes.
Intravascular injection of diatrizoate also opacifies those vessels in the path of flow of the medium, permitting visualization until the circulating blood dilutes the concentration of the medium. Thus selective angiography may be performed following injection directly into veins or arteries.

Computed Tomography

RenoCal-76 enhances computed tomographic brain scanning through augmentation of radiographic efficiency. The degree of enhancement of visualization of tissue density is directly related to the iodine content in an administered dose; peak iodine blood levels occur immediately following rapid injection of the dose. These levels fall rapidly within five to ten minutes. This can be accounted for by the dilution in the vascular and extracellular fluid compartments which causes an initial sharp fall in plasma concentration. Equilibration with the extracellular compartments is reached in about ten minutes; thereafter, the fall becomes exponential. Maximum contrast enhancement frequently occurs after peak blood iodine levels are reached. The delay in maximum contrast enhancement can range from five to forty minutes, depending on the peak iodine levels achieved and the cell type of the lesion. This lag suggests that radiographic contrast enhancement is at least in part dependent on the accumulation of iodine within the lesion and outside the blood pool, although the mechanism by which this occurs is not clear. The radiographic enhancement of nontumoral lesions, such as arteriovenous malformations and aneurysms is probably dependent on the iodine content of the circulating blood pool.

INDICATIONS

RenoCal-76 is indicated in excretion urography, nephrotomography, aortography, pediatric angiocardiography, peripheral arteriography, selective renal arteriography, selective visceral arteriography, selective coronary arteriography, selective coronary arteriography combined with left ventriculography, and intravenous digital subtraction angiography (DSA).

Computed Tomography

RenoCal-76 is also indicated for radiographic contrast enhancement in computed tomography (CT) of the brain. Contrast enhancement is advantageous in delineating or ruling out disease in suspicious areas which may otherwise not have been satisfactorily visualized.

Tumors
RenoCal-76 may be useful to demonstrate the presence and extent of certain malignancies such as: gliomas including malignant gliomas, glioblastomas, astrocytomas, oligodendrogliomas and gangliomas; ependymomas; medulloblastomas; meningiomas; neuromas; pinealomas; pituitary adenomas; craniopharyngiomas; germinomas; and metastatic lesions.

The usefulness of contrast enhancement for the investigation of the retrobulbar space and in cases of low grade or infiltrative glioma has not been demonstrated.

In cases where lesions have calcified, there is less likelihood of enhancement. Following therapy, tumors may show decreased or no enhancement.

Non-Neoplastic Conditions
The use of RenoCal-76 may be beneficial in the enhancement of images of lesions not due to neoplasms. Cerebral infarctions of recent onset may be better visualized with the contrast enhancement, while some infarctions are obscured if a contrast medium is used. The use of RenoCal-76 improved the contrast enhancement in approximately 60 percent of cerebral infarctions studied from one week to four weeks from the onset of symptoms.

Sites of active infection also will produce contrast enhancement following contrast medium administration.

Arteriovenous malformations and aneurysms will show contrast enhancement. In the case of these vascular lesions, the enhancement is probably dependent on the iodine content of the circulating blood pool.

Hematomas and intraparenchymal bleeders seldom demonstrate any contrast enhancement. However, in cases of intraparenchymal clot, for which there is no obvious clinical explanation, contrast medium administration may be helpful in ruling out the possibility of associated arteriovenous malformation.

The opacification of the inferior vermis following contrast medium administration has resulted in false-positive diagnoses in a number of normal studies.

CONTRAINDICATIONS
RenoCal-76 is contraindicated for use in intrathecal procedures.
This preparation is contraindicated in patients with a hypersensitivity to salts of diatrizoic acid.
Urography and nephrotomography are contraindicated in patients with anuria.

WARNINGS

Severe Adverse Events—Inadvertent Intrathecal Administration
Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These serious adverse reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to insure that this drug product is not inadvertentlyadministered intrathecally.
The possibility exists for inadvertent administration into the intrathecal space during epidural administrations. Therefore, epidural administration procedures, such as pain management catheter placement, should not be performed with use of this product.

General
Ionic iodinated contrast media inhibit blood coagulation, *in vitro*, more than nonionic contrast media. Nonetheless, it is prudent to avoid prolonged contact of blood with syringes containing ionic contrast media.
Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. Numerous factors, including length of procedure, catheter and syringe material, underlying disease state, and concomitant medications may contribute to the development of thromboembolic events. For these reasons, meticulous angiographic techniques are recommended including close attention to guidewire and catheter manipulation, use of manifold systems and/or three way stopcocks, frequent catheter flushing with heparinized saline solutions, and minimizing the length of the procedure. The use of plastic syringes in place of glass syringes has been reported to decrease but not eliminate the likelihood of *in vitro* clotting.
A definite risk exists in the use of intravascular contrast agents in patients who are known to have multiple myeloma. In such instances there has been anuria resulting in progressive uremia, renal failure and eventually death. Although neither the contrast agent nor dehydration has separately proved to be the cause of anuria in myeloma, it has been speculated that the combination of both may be the causative factor. The risk in myelomatous patients is not a contraindication to the procedures; however, partial dehydration in the preparation of these patients for the examination is not recommended since this may predispose to the precipitation of myeloma protein in the renal tubules. No form of therapy, including dialysis, has been successful in reversing this effect. Myeloma, which occurs most commonly in persons over age 40, should be considered before intravascular administration of a contrast agent.
Administration of radiopaque materials to patients known or suspected to have pheochromocytoma should be performed with extreme caution. If, in the opinion of the physician, the possible benefits of such procedures outweigh the considered risks, the procedures may be performed; however, the amount of radiopaque medium injected should be kept to an absolute minimum. The blood pressure should be assessed throughout the procedure and measures for treatment of a hypertensive crisis should be available.
Contrast media have been shown to promote the phenomenon of sickling in individuals who are homozygous for sickle cell disease when the material is injected intravenously or intra-arterially.

Since iodine-containing contrast agents may alter the results of thyroid function tests, such tests, if indicated, should be performed prior to the administration of this preparation.
A history of sensitivity to iodine *per se* or to other contrast agents is not an absolute contraindication to the use of diatrizoate, but calls for extreme caution in administration.
In patients with subarachnoid hemorrhage, a rare association between contrast administration and clinical deterioration, including convulsions and death, has been reported; therefore, administration of intravascular iodinated ionic contrast media in these patients should be undertaken with caution.
The inherent risks of *angiocardiography* in cyanotic infants and patients with chronic pulmonary emphysema must be weighed against the necessity for performing this procedure. In *pediatric angiocardiography*, a dose of 10 to 20 mL may be particularly hazardous in infants weighing less than 7 kg. This risk is probably significantly increased if these infants have preexisting right heart“strain,” right heart failure, and effectively decreased or obliterated pulmonary vascular beds.
Urography and nephrotomography should be performed with extreme caution in patients with severe concomitant hepatic and renal disease.
Selective visceral arteriography should be performed with extreme caution in patients with severe generalized atherosclerosis, specifically with plaques or aneurysms at the level of the iliac or femoral arteries.
Selective coronary arteriography should be performed only in selected patients and those in whom the expected benefits outweigh the procedural risk.

PRECAUTIONS
Diagnostic procedures which involve the use of diagnostic radiopaque contrast agents should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed. Appropriate facilities should be available for coping with any complication of the procedure, as well as for emergency treatment of severe reactions to the contrast agent itself. After parenteral administration of a radiopaque agent, competent personnel and emergency facilities should be available for at least 30 to 60 minutes since severe delayed reactions have occurred (see**ADVERSE REACTIONS**).
Severe, life-threatening reactions suggest hypersensitivity to the radiopaque agent, which has prompted the use of several pretesting methods, none of which can be relied upon to predict severe reactions. Many authorities question the value of any pretest. A history of bronchial asthma or allergy, a family history of allergy, or a previous reaction to a contrast agent warrant special attention. Such a history, by suggesting histamine sensitivity and a consequent proneness to reactions, may be more accurate than pretesting in predicting the likelihood of a reaction, although not necessarily the severity or type of reaction in the individual case.
The sensitivity test most often performed is the slow injection of 0.5 to 1.0 mL of the radiopaque medium, administered intravenously, prior to injection of the full diagnostic dose. It should be noted that the absence of a reaction to the test dose does not preclude the possibility of a reaction to the full diagnostic dose. If the test dose causes an untoward response of any kind, the necessity for continuing with the examination should be carefully reevaluated and, if it is deemed essential, the examination should be conducted with all possible caution. In rare instances reactions to the test dose itself may be extremely severe; therefore, close observation of the patient, and facilities for emergency treatment, appear indicated.
Renal toxicity has been reported in a few patients with liver dysfunction who were given oral cholecystographic agents followed by urographic agents. Administration of RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) should therefore be postponed in any patient with a known or suspected hepatic or biliary disorder who has recently taken a cholecystographic contrast agent.
Caution should be exercised with the use of radiopaque media in severely debilitated patients and in those with marked hypertension.
The possibility of thrombosis should be borne in mind when percutaneous techniques are employed.
Consideration must be given to the functional ability of the kidneys before injecting this preparation.
Contrast agents may interfere with some chemical determinations made on urine specimens; therefore, urine should be collected before administration of the contrast medium or two or more days afterwards.
The following precautions pertain to specific procedures:
Excretion urography and nephrotomography: Acute renal failure has been reported in diabetic patients with diabetic nephropathy and susceptible nondiabetic patients (often elderly with preexisting renal disease) following urographic procedures. Therefore, careful consideration should be given to the increased potential risk in these patients prior to performing either procedure. In *excretion urography* adequate visualization may be difficult or impossible to attain in uremic patients or others with severely impaired renal function (see **CONTRAINDICATIONS**). In *nephrotomography*, although azotemia is not considered a contraindication, care is required in patients with advanced renal failure. Preparatory partial dehydration is not recommended in these patients, and their urinary output should be observed for one to two days following the procedure.
Aortography: Repeated intra-aortic injections may be hazardous.
Pediatric angiocardiography: Repeated injections may be hazardous particularly in infants weighing less than 7 kg (see **WARNINGS**).
Peripheral arteriography: Hypotension or moderate decreases in blood pressure seem to occur frequently with intra-arterial (brachial) injections; therefore, the blood pressure should be monitored during the immediate ten minutes after injection; this blood pressure change is transient and usually requires no treatment.

Selective coronary arteriography: It is recommended that the procedure should not be performed for approximately four weeks following the diagnosis of myocardial infarction. Mandatory prerequisites to the procedure are experienced personnel, ECG monitoring apparatus, and adequate facilities for immediate resuscitation and cardioversion.
Intravenous digital subtraction angiography: The dose is usually administered mechanically under high pressure; rupture of smaller peripheral veins can occur. This may be avoided by using an intravenous catheter threaded proximally beyond larger tributaries or, in the case of the antecubital vein, into the superior vena cava; the femoral vein is used sometimes. It may be desirable to administer a test dose by manual injection prior to the diagnostic dose to ensure that the catheter has been properly positioned.

Usage In Pregnancy
Safety for use during pregnancy has not been established; therefore, this preparation should be used in pregnant patients only when, in the judgment of the physician, its use is deemed essential to the welfare of the patient.

ADVERSE REACTIONS
Mild, moderate, and sometimes severe adverse reactions may occur associated with the procedure and/or the contrast media. Reactions known to occur with parenteral administration of iodinated ionic contrast media (see the listing below) are possible with a nonionic agent. Approximately 95 percent of adverse reactions accompanying the use of other water-soluble intravascularly administered contrast agents are mild to moderate in degree. However, severe and life-threatening reactions and fatalities, mostly of cardiovascular origin, have occurred.
Reported incidences of death from the administration of other iodinated contrast media range from 6.6 per 1 million (0.00066 percent) to 1 in 10,000 patients (0.01 percent). Most deaths occur during injection or 5 to 10 minutes later, the main feature being cardiac arrest with cardiovascular disease as the main aggravating factor. Isolated reports of hypotensive collapse and shock are found in the literature. The incidence of shock is estimated to be 1 out of 20,000 (0.005 percent) patients.
Nausea, vomiting, flushing, or a generalized feeling of warmth are the reactions seen most frequently with intravascular injection. Symptoms which may occur are chills, fever, sweating, headache, dizziness, pallor, weakness, severe retching and choking, wheezing, a rise or fall in blood pressure, facial or conjunctival petechiae, urticaria, pruritus, rash, and other eruptions, edema, cramps, tremors, itching, sneezing, lacrimation, etc. Antihistaminic agents may be of benefit; rarely such reactions may be severe enough to require discontinuation of dosage.
Although local tissue tolerance is usually good, there have been a few reports of a burning or stinging sensation or numbness and of venospasm or venous pain, and partial collapse of the injected vein. Neutropenia or thrombophlebitis may occur.
Severe reactions which may require emergency measures may take the form of a cardiovascular reaction characterized by peripheral vasodilatation with resultant hypotension and reflex tachycardia, dyspnea, agitation, confusion and cyanosis progressing to unconsciousness. Or, the histamine-liberating effect of these compounds may induce an allergic-like reaction which may range in severity from rhinitis or angioneurotic edema to laryngeal or bronchial spasm or anaphylactoid shock.
Temporary renal shutdown or other nephropathy may occur.
Adverse reactions may sometimes occur as a consequence of the procedure for which the contrast agent is used. Adverse reactions in *excretion urography* have included cardiac arrest, ventricular fibrillation, anaphylaxis with severe asthmatic reaction, and flushing due to generalized vasodilatation. Reactions following higher doses for *nephrotomography* are usually mild and transitory and do not appear to occur more frequently or severely than those induced by doses for excretion urography. Nausea, vomiting, flushing, or a generalized feeling of warmth are the reactions seen most frequently. In *aortography* , the risks of procedures include injury to the aorta and neighboring organs, pleural puncture, renal damage including infarction and acute tubular necrosis with oliguria and anuria, accidental selective filling of the right renal artery during the translumbar procedure in the presence of preexistent renal disease, retroperitoneal hemorrhage from the translumbar approach, spinal cord injury and pathology associated with syndrome of transverse myelitis, generalized petechiae, and death following hypotension, arrhythmia, and anaphylactoid reactions. Adverse reactions in *pediatric angiocardiography* have included arrhythmia and death. During*peripheral arteriography*, complications have occurred including hemorrhage from the puncture site, thrombosis of the vessel, and brachial plexus palsy following axillary artery injections. During*selective coronary arteriography* and *selective coronary arteriography combined with left ventriculography*, most patients will have transient ECG changes. Transient arrhythmias may occur infrequently. Ventricular fibrillation may result from manipulation of the catheter during the procedure or administration of the medium. Other reactions may include hypotension, chest pain, and myocardial infarction. Transient elevation of CPK (creatine phosphokinase) has occurred in approximately 30 percent of the patients tested. Fatalities have been reported. Complications due to the procedure include hemorrhage, thrombosis, pseudoaneurysms at the puncture site, and dislodgment of arteriosclerotic plaques. Dissection of the coronary vessels and transient sinus arrest have occurred rarely.
Adverse reactions in *selective renal arteriography* include nausea, vomiting, hypotension and hypertension. Post-arteriographic changes in laboratory studies include transient elevations in BUN, serum creatinine and glucose.
Complications due to the procedure during *selective visceral arteriography* include hematomas, thrombosis, pseudoaneurysms at injection site, and dislodgment of arteriosclerotic plaques. Other reactions may include urticaria, hypotension, hypertension, and insignificant changes in renal function and liver chemistry tests.

DOSAGE AND ADMINISTRATION

RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) should be at body temperature when injected, and may need to be warmed before use. Syringes should be rinsed as soon as possible after injection to prevent freezing of the plunger. **Withdrawal of the contrast agent should be accomplished under aseptic conditions with sterile needle and syringe.**

Excretion Urography and Nephrotomography

Patient Preparation

Appropriate preparation of the patient is desirable for optimal results. A laxative the night before the examination, a low residue diet the day before, and low liquid intake for 12 hours prior to the procedure may be used to clear the gastrointestinal tract and to induce a partial dehydration which is believed to increase the urinary concentration of the contrast medium. Enemas are to be avoided to prevent rehydration.

Preparatory partial dehydration is not recommended in infants, young children, the elderly, those with impaired renal function, or azotemic patients (especially those with polyuria, oliguria, diabetes, advanced vascular disease, or preexisting dehydration, see **PRECAUTIONS**). The undesirable dehydration in these patients may be accentuated by the osmotic diuretic action of the medium.

In uremic patients partial dehydration is not necessary and maintenance of adequate fluid intake is particularly desirable.

Excretion Urography

The usual intravenous dose for patients aged 16 years or more is 20 mL, but 30 to 40 mL have been used. Children require less in proportion to weight: Under 6 months of age–4 mL; 6 to 12 months–6 mL; 1 to 2 years–8 mL; 2 to 5 years–10 mL; 5 to 7 years–12 mL; 8 to 10 years–14 mL; 11 to 15 years–16 mL.

The preparation is given by intravenous injection. If flushing or nausea occurs during administration, injection should be slowed or briefly interrupted until the side effects have disappeared.

A scout film should be made before the contrast medium is administered. To allow for individual variation, several films should be exposed beginning approximately five minutes after injection. In patients with renal dysfunction optimal visualization may be delayed until 30 minutes or more after injection.

NOTE: In infants and children and in certain adults, the medium may be injected intramuscularly. The suggested dose is the same as the intravenous dose divided and given bilaterally in the gluteal muscles. Radiographs should be taken at 20, 40, and 60 minutes after the medium is injected.

Nephrotomography

Nephrotomography may be performed when prior urography has failed to provide diagnostic information. At high dosage, RenoCal-76 may be used to intensify and prolong the nephrographic effect (especially with tomography) when the prime purpose is examination of the renal parenchyma. For example, this method may be employed in the preoperative differentiation of renal masses and damage to the renal parenchyma such as that caused by infarcts or infections.

The suggested dose is 100 mL administered by rapid bolus intravenous injection or intravenous infusion. The usual time interval for administration of the dose has ranged up to four minutes for bolus injections and up to 15 minutes for infusions, depending on the volume of the solution. During the period of intense blush of the renal parenchyma (nephrographic phase), tomographic “cuts” spaced 1 cm apart are obtained through the entire thickness of both kidneys. The complete film series should be exposed within 60 to 90 seconds following administration of the dose for best results. The number of “cuts” (longitudinal) will vary in individual cases.

Aortography

RenoCal-76 injected into the aorta by the translumbar or retrograde method of administration, permits radiographic visualization of the aorta, its major branches and the abdominal arteries. An incidental nephrogram is obtained as the contrast medium travels through the renal vasculature, provided it has been injected above the renal artery.

Patients should be prepared in a manner similar to that used for intravenous urography. Premedication with a suitable barbiturate is generally indicated.

As in any form of surgery, certain hazards accompany aortographic procedures (see **ADVERSE REACTIONS**).

For adults and children over 16 years of age, the usual dose is 15 to 40 mL as a single injection, repeated if indicated. Children require less in proportion to weight. Doses up to a total of 160 mL have been given safely.

Since the medium is given by rapid injection in this procedure, patients should be watched for untoward reactions during the injection. Unless general anesthesia is employed, patients should be warned that they may feel some transient pain or burning during the injection followed by a feeling of warmth immediately afterward.

A scout film should be made before the contrast agent is administered. The first radiogram should be taken as the last few mL of the contrast medium are being injected.

Pediatric Angiocardiography
Angiocardiography, with RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) may be performed by injection into a large peripheral vein or by direct catheterization of the heart. An excretory urogram can be obtained 10 to 15 minutes after injection of the contrast medium since it is concentrated in and eliminated by the kidneys.
Patients should be prepared in a manner similar to that used for intravenous urography. Appropriate preanesthetic medication should be given.
Clinical studies in man and related animal experiments, have suggested that the hypertonicity of diatrizoate contrast agents produces significant hemodynamic effects, especially in right-sided injections. Large volumes of such agents cause a drop in peripheral arterial and systemic pressures and cardiac output, a rise in pulmonary arterial and right-heart pressures, bradycardia, and regular ectopic beats. Resulting effects on peripheral arterial and pulmonary arterial pressures are postulated to be due to mechanical blockage of the pulmonary vascular bed and clumping of red cells.
Hypertonic solutions cause a decrease in hematocrit *in vitro* and *in vivo*, and shrinkage of red blood cells.
It is suggested that hemodynamic changes be monitored and that pressures considered abnormal under roentgenographic conditions be allowed to return to a preangiographic level before continuation of radiopaque injection; this usually takes 15 minutes.
The suggested single dose for children *under* five years of age is 10 to 20 mL, depending on the size of the child. For children 5 to 10 years of age, single doses of 20 to 30 mL are recommended. Doses up to a total of 100 mL have been given safely.
Since the contrast medium is given by rapid injection, the patient should be watched for untoward reactions during the injection. Some patients not under general anesthesia may experience a feeling of bodily warmth, tightness of the chest, and throbbing headache. All these sensations are of short duration. Transient nausea and vomiting may occur in some patients.
A preliminary control film should be made in the usual manner.

Peripheral Arteriography
Appropriate preparation of the patient is indicated, including suitable premedication. For visualization of an entire extremity, a single dose of 20 to 40 mL is suggested; for the upper or lower half of the extremity only, 10 to 20 mL is usually sufficient.
Injection is made into the femoral or subclavian artery by the percutaneous or operative method. Because the contrast agent is given by rapid injection, flushing of the skin may occur. Patients not under general anesthesia may experience nausea and vomiting or a transient feeling of warmth. Vascular spasm is not likely to occur.
A scout film should be made routinely before administering the contrast medium. Radiograms of the upper half of the extremity are taken while the last few mL are being injected, followed by radiograms of the lower half of the extremity a few seconds later.

Selective Renal Arteriography
The usual dose is 5 to 10 mL injected into either or both renal arteries via femoral artery catheterization. This dose may be repeated as necessary; doses up to 60 mL have been given.

Selective Visceral Arteriography
The usual dose is 30 to 50 mL injected into the appropriate visceral artery (celiac axis and its branches, superior mesenteric artery, or inferior mesenteric artery) via femoral artery catheterization. This may be repeated as necessary. It is recommended that the combined total dose not exceed 250 mL.

Selective Coronary Arteriography
The usual dose is 4 to 10 mL injected into a coronary artery. This dose, repeated as necessary, may be administered into each coronary artery; doses up to a total of 150 mL have been given. Patients should be monitored continuously by ECG throughout the procedure.

Selective Coronary Arteriography Combined with Left Ventriculography
For left ventriculography the usual dose is 35 to 50 mL injected into the left ventricle. This may be repeated as necessary. It is recommended that the total dose for combined selective coronary arteriography and left ventriculography not exceed 200 mL.

Intravenous Digital Subtraction Angiography (DSA)
Diagnostic-quality arteriograms can be obtained by intravenous administration of RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) and employment of digital subtraction and computer imaging enhancement equipment. This technique has the advantage of being less invasive than the corresponding intra-arterial selective catheter placement technique. The dose is administered into a peripheral vein by mechanical pressure injection, although sometimes by rapid manual injection (see **PRECAUTIONS**). This technique has been used most frequently to visualize the ventricles, the aorta and most of its larger branches including the carotid, coronary, pulmonary, intracranial, ophthalmic, vertebral, renal, celiac, mesenterics and the major peripheral arteries of the limbs, and for visualization of graft patency.
The usual dose of RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) per bolus injection ranges between 30 and 60 mL (approx. 0.5 to 1 mL/kg) administered intravenously at a rate of 7.5 to 30 mL per second. When indicated, multiple bolus injections of RenoCal-76 (200 mL maximum total volume) may be administered; dosage and rate of injection are generally

determined by considerations of age, weight, renal function and arterial site to be studied, as well as by type of equipment and technique to be used. First exposures are made on the basis of calculated circulation time.

Computed Tomography
The suggested dose is 50 to 125 mL by intravenous administration; scanning may be performed immediately after completion of administration. Doses for children should be proportionately less, depending on age and weight.

Patient Preparation
No special patient preparation is required for contrast enhancement of CT brain scanning. However, it is advisable to insure that patients are well hydrated prior to examination.

HOW SUPPLIED
RenoCal-76 (Diatrizoate Meglumine and Diatrizoate Sodium Injection USP) is available in packages of:

Twenty-five single dose 50 mL vials (NDC 0270-0860-20)

Ten single dose 100 mL bottles (NDC 0270-0860-30)

Ten single dose 150 mL bottles (NDC 0270-0860-40)

Ten single dose 200 mL bottles (NDC 0270-0860-50)

Storage
The preparation should be stored at 20-25°C (68-77°F) [See USP]; protected from light. If precipitation or solidification has occurred due to storage in the cold, immerse the container in hot water and shake intermittently to redissolve any solids. The product should not be used if a precipitate does not dissolve.

Rx only
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